REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and the following remarks.

I. Status of the Claims

Claims 1, 3-6 and 8-20 are currently pending in the application, with claim 1 being the independent claim. Claims 2 and 7 were previously cancelled without prejudice to or disclaimer of the subject matter therein. Claims 1, 11-12 and 17 are amended.

Claim 1 is amended to correct a spelling error. Support for the amendment to claim 1 may be found, *inter alia*, in claim 6 as previously presented.

Claim 11 is amended to delete the phrase "and/or flavourings which are suitably spicy and anti-oxidative with regard to unsaturated fatty acids".

Claim 12 is amended to insert a comma between "D" and "E".

Claim 17 is amended to delete the phrase "(nicotine amide)".

These amendments do not introduce any new matter into the application and their entry is respectfully requested.

II. The Objections to the Claims

The Office Action, at page 2, objects to claim 1 for allegedly failing to recite "alpha-linolenic acid". Further, the Office Action objects to claim 12 as allegedly failing to introduce a comma between "D" and "E".

As the foregoing amends claim 1 to recite "alpha-linolenic acid" and amends claim 12 by inserting a comma, these objections are now moot. Reconsideration and withdrawal of this ground of objection are therefore respectfully requested.

III. The Rejection Under 35 U.S.C. § 112, First Paragraph

The Office Action, at pages 2-5, rejects claims 11-13 under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. Specifically, the Office Action alleges that the specification fails to provide adequate support for the claimed genus of flavorings that are suitably spicy and anti-oxidative with regard to unsaturated fatty acids. Applicant respectfully traverses this ground of rejection.

Solely to advance prosecution, and not in acquiescence with the rejection, Applicant has removed the phrase "flavorings which are suitably spicy and anti-oxidative with regards to unsaturated fatty acids." Accordingly, this rejection is now moot. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

IV. The Rejections Under 35 U.S.C. § 112, Second Paragraph

The Office Action, at pages 5-7, rejects claims 11-13 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for reciting the phrase "flavorings which are suitably spicy and anti-oxidative with regards to unsaturated fatty acids." Further, the Office Action rejects claims 13 and 17 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for reciting parenthetical limitations. Applicant respectfully traverses this ground of rejection.

Solely to advance prosecution, and not in acquiescence with the rejection, the foregoing amends claim 11 to delete the phrase "flavorings which are suitably spicy and anti-oxidative with regards to unsaturated fatty acids." Further, the foregoing amends claim 17 to remove the phrase "(nicotine amide)". Thus, these rejections are now moot.

Regarding claims 13, the claim is readily understandable to one of skill in the art. In the current context, the term "1 to 5 μg" corresponds to an equivalent dosage of 40 to 200 I.U. of vitamin D3. Accordingly, claim 13 is not indefinite.

Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

V. The Rejection Under 35 U.S.C. § 102(b)

The Office Action, at pages 7-9, rejects claims 1, 3, 6 and 11-12 under 35 U.S.C. § 102(b) as allegedly being anticipated by Alexander *et al.* (EP 0691079 A2; 1996) ("Alexander") in light of Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care, 5(2)*:127-132, March 2002; abstract only) ("Brenna").

According to the Office Action, Alexander discloses an enteral composition for providing nutrition or nutritional supplementation to a diabetic patient comprising a fat source comprising 20% MCT, long chain triglycerides provided in sunflower oil, which oil provides linoleic acid and linolenic acid, mono-unsaturated fatty acids, a protein component, a carbohydrate component, flavoring, vanilla, vitamins and minerals.

The Office Action acknowledges that Alexander fails to teach eicosapentaen acid and/or docosahexaen acid. Nevertheless, the Office Action relies on the disclosure of Brenna, that teaches that α-linolenic acid is a precursor that can be converted into eicosapentaen acid and docosahexaen acid. From these teachings, the Office Action then infers that eicosapentaen acid and docosahexaen acid are necessarily present in the composition disclosed by Alexander. Applicant respectfully traverses this ground of rejection.

A. Summary of the Claimed Invention

Claim 1 recites a method for supplementing the diet of a subject with diabetes mellitus comprising administering to the subject medium-chain triglycerides or a composition comprising medium-chain triglycerides in an amount sufficient to regulate and normalize fat metabolism in the subject, wherein the composition contains a fat phase which comprises: (a) 10 to 30%

medium-chain triglycerides; (b) at least one monounsaturated fatty acid; (c) linoleic acid; (d) α-linolenic acid; and (e) ***eicosapentaen acid and/or docosahexaen acid*** as multiple unsaturated triglycerides.

B. The Cited References Fail to Teach Each and Every Element of the Claimed Invention

Alexander discloses a moderate to low carbohydrate, high fat enteral formulation. Alexander fails to teach or suggest a composition containing a fatty acid comprising eicosapentaen acid and/or docosahexaen acid.

Brenna does not remedy the deficiencies of Alexander. Brenna fails to teach or suggest a composition containing a fatty acid comprising eicosapentaen acid and/or docosahexaen acid. Brenna teaches that alpha-linolenic acid is the principal precursor for long-chain polyunsaturated fatty acids, of which eicosapentaen acid and docosahexaenoic acid are the most prevalent, and states that *whole body conversion of alpha-linolenic acid to docosahexaenoic acid is below 5% in humans, and depends on the concentration of n-6 fatty acids and long chain polyunsaturated fatty acids in the diet.*

This conversion of alpha-linolenic acid is effected – very slowly – in the body with the help of desaturase enzymes, which are found in many tissues. The composition disclosed by Alexander does not contain any desaturase enzyme, which would allow this conversion to take place. Accordingly, the cited references fail to anticipate the claimed invention.

Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

VI. <u>The Rejections Under 35 U.S.C. § 103(a)</u>

A. The Rejection of Claims 1, 3, 6, 9 and 11-19

The Office Action, at pages 9-12, rejects claims 1, 3-6, 9 and 11-19 under 35 U.S.C. § 103, as allegedly being unpatentable over Alexander *et al.* (EP 0691079 A2; 1996) ("Alexander") in light of Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care, 5(2)*:127-132, March 2002; abstract only) ("Brenna"). Applicant respectfully traverses this ground of rejection.

The inability of Alexander and Brenna to teach or suggest the invention of claims 1, 3, 6 and 11-12 is demonstrated above. One of ordinary skill in the art would have known that without the addition of desaturase enzyme, alpha-linolenic acid cannot be converted into eicosapentaen acid and/or docosahexaen acid. Thus, the composition disclosed by Alexander contains no eicosapentaen acid and/or docosahexaen acid.

At least for the reasons stated above, the cited references fail to render obvious the claimed invention, and this rejection is improper. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

B. The Rejection of Claims 1, 3, 6, 9 and 11-19

The Office Action, at pages 12-15, rejects claims 1, 3-6, 8-10 and 20 under 35 U.S.C. § 103, as allegedly being unpatentable over Alexander *et al.* (EP 0691079 A2; 1996) ("Alexander") in light of Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care, 5(2)*:127-132, March 2002; abstract only) ("Brenna"), in view of Madigan *et al.* ("Dietary Unsaturated Fatty Acids in Type 2 Diabetes", *Diabetes Care 23*:1472-1477; 2000) ("Madigan"), Heine *et al.* ("Linoleic-Acid-Enriched Diet: Long-Term Effects on Serum Lipoprotein and Apolipoprotein Concentrations and Insulin Sensitivity in Noninsulin-Dependent Diabetic Patients", *Am J Clin Nutr, 49(3)*:448-456; 1989, Abstract Only) ("Heine") and the Merck Index ("Citric Acid", Monograph 2328, 1989; page 363). Applicant respectfully traverses this ground of rejection.

The inability of Alexander and Brenna to teach or suggest the invention of claims 1, 3, 6, 9 and 11-19 is demonstrated above. The additional references, Madigan, Heine and the Merck Index, do not remedy the deficiencies of Alexander and Brenna, as none of these references discloses nutritional compositions comprising eicosapentaen acid and/or docosahexaen acid.

The Office Action alleges that in view of the teachings of Madigan and Heine, one of ordinary skill in the art would have been motivated to use linoleic acid as a major component in the nutritional composition, because of its anti-atherosclerotic effect in patients suffering from type 2 diabetes, and to add oleic acid in a significant quantity, because oleic acid-rich diets "***were also known to reduce atherogenic risk in a manner similar to linoleic acid-rich diets***" (*see* pages 13-14). The Office Action allegations, however, lack well-founded reasons.

Contrary to the Office Action's allegations, Heine and Madigan *teach against the claimed invention*. In fact, Heine teaches that a linoleic-enriched diet in patients with NIDD causes a less atherogenic lipoprotein profile than a diet with a low polyunsaturated to saturated fat ratio, but *does not influence glycemic control and carbohydrate tolerance*. Madigan teaches that in type 2 diabetes *an oleic acid-rich Mediterranean-type diet versus a linoleic acid-enriched diet may reduce the risk of atherosclerosis*, and concludes that ***linoleic acid may not be the best option for people with type 2 diabetes, since a linoleic acid-rich diet is associated with increased fasting insulin and glucose levels, increased postprandial lipoproteins and significantly higher plasma and LDL cholesterol levels, all of which are associated with atherosclerotic risk*** (*see* page 1476, bottom of middle column). Thus, both Heine and Madigan teach against the use of linoleic acid in supplementing the diet of type 2 diabetes subjects.

Accordingly, the artisan skilled in the art would have **not** been motivated to use linoleic acid as a major component in a composition for supplementing the diet of a subject with diabetes mellitus, for at least **two** reasons. First, one of ordinary skill in the art, in view of the teachings of Heine, that a linoleic-enriched diet has no effect on glycemic control and carbohydrate tolerance, would have been led to think that linoleic acid would not help normalize blood glucose level in a subject with diabetes. Second, one of ordinary skill in the art, in view of the teachings

of Madigan that linoleic acid may not be the best option for people with type 2 diabetes, would not have considered supplementing the diet of a subject with diabetes with a composition containing linoleic acid as a major component.

At least for the reasons stated above, the cited references fail to render obvious the claimed invention, and this rejection is improper. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed or rendered moot. Therefore, the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant(s) hereby petition(s) for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 2 November 2007

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